

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | Scott Schewe and Victor Schoenle and Jan Weber |
| Application No.: | 10/617428 |
| Filed: | July 10, 2003 |
| For: | MEDICAL DEVICE TUBING WITH DISCRETE ORIENTATION REGIONS |
| Examiner: | Jeffrey Michael Wollschlager |
| Group Art Unit: | 1791 |

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Docket No.: S63.2B-10941-US01

REPLY BRIEF

This is in reply to the Examiner's Answer Mailed August 1, 2008 and is being filed on or before the due date of October 1, 2008.

The Examiner's Answer states on page 8:

... The examiner agrees that the slating process whereby the waist, cone or body portions are defined is an inherent process (i.e., no additional positive/manipulative steps are performed). ...

this fundamentally distorts the argument presented in the Appeal Brief. The Examiner ignores the fact that the applicant points out that slating is an event (or events) that assigns a particular *relationship* between locations on the tubing segment and the respective body, cone, and waist portions which are to be formed therefrom. Thus, while slating can occur inherently in the course of processing from tubing to balloon, before the balloon is blown the relationship is in fact *established*. The event (or events) that define this relationship between locations constitutes the slating recited in the claimed method.

If the tubing is used to form some other article such as a catheter tip or shaft the recited slating *does not occur*, explicitly or inherently. When tubing is processed into such articles, the recited relationship between tubing locations and balloon cone, waist and body portions is *never established*. In particular, the assignment of different regions of the tubing segment in Pepin's Fig. 7 to catheter tip portions does not provide the slating recited in claim 23.

The Examiner's Answer also tries to sell the argument that Pepin's

mention of "balloon catheters" somehow necessarily teaches to make a balloon parison of the Pepin tubing. This is simply not true. Balloon catheters, balloons and balloon parisons are not the same things. Balloon catheters have tips, which are typically designed to be soft, like the tips depicted by Pepin. Those tips are not balloons and they are not balloon parisons. They also have catheter shafts, and again the shafts are not balloons or balloon parisons. Balloon catheters *do not* have balloon parisons. Pepin's teaching that the invention pertains to balloon catheters leads one to prepare the balloon catheters with the catheter tips, prepared as illustrated in Figure 7, or to prepare the balloon catheters with multilayer shafts, as in Figs. 8A-8C, but it is a completely fictional reconstruction of Pepin to say that it teaches balloon parisons.

The Examiner's Answer nevertheless contends on page 10:

... looking at Figure 7 of Pepin et al., the examiner submits that one having ordinary skill would immediately understand and interpret Pepin et al. to teach that the cuts (80) need only be made in a different location to produce the explicitly recited balloon catheter of Pepin et al. instead of the exemplified catheter tip.

This is complete and utter nonsense. The location of the cuts (80) will not be any different if the tubing segment depicted in Figure 7 is used to prepare a balloon catheter. The structure produced will be the balloon catheter tip. No modification of the cut location is necessarily indicated, or even suggested, by a use of that tip on

a "balloon catheter."

The continued assertion on page 10 of the Examiner's Answer that the slating relationship of claim 24 is met by Pepin begs the question. Where? The Examiner's Answer just admitted in the previous paragraph that the cuts 80 of Figure 7 are *not* in the right location. There is no reasonable argument that Pepin teaches alternate use of that tubing as a balloon *parison*. Slating segments of tubing for particular regions of a catheter tip, as is specifically done in Pepin's Figure 7, actually leads away from slating the same segments for particular regions of a balloon since the functions of the balloon and the catheter tip of a balloon catheter are very different.

The claims at issue are to a method of preparing balloon parisons. Once again, balloon parisons are predecessors of balloons, not the balloons themselves and balloon parisons are not parts of a "balloon catheter." The Examiner's Answer demonstrates that the Examiner is just waiving the term "balloon catheter" wildly around in the air and hoping that the Board will equate the term with balloon parison. The skilled person knows the difference. The Board should not sustain the rejection of claims 23-25.

Regarding claim 43, the claim is to a method, not the product of the method. The Examiner explicitly relies on an inherency argument directed to the products, not to the process. The plain language of the claim specifies that the *choice criteria* to be used is elongation at yield. The Examiner's Answer on page 11 admits that the choice criteria of Pepin et al is a desired dimension. In the language of claim 43, dimension is the *basis* of the alteration of the drawing rate. To the extent that different elongation may be produced, this would be a *result* of the alteration but not the *basis* of the alteration. The *method* is actually different when one uses a measurement of elongation rather than a measurement of dimension as the criteria for alteration of drawing rate, regardless of whether or not the products are distinguishable.

Regarding claims 44 and 45, the Examiner's Answer on page 11 ignores that the claim has a quantitative relationship in the selection. Even if inherency could properly be found against claim 43, the Examiner would have to provide a reason to believe that the difference in orientation produced by Pepin's changes in drawing rate necessarily meet the respective 20% and 30% elongation differences of these claims. The Examiner's Answer points to nothing in Pepin or Chen that arguably shows this would necessarily be so.

The Examiner's Answer fails to demonstrate that all of the steps of the recited method in any of the rejected claims are performed in Pepin when viewed in light of Chen et al. The Board is again requested to reverse the anticipation rejections and allow the application to issue.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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By: /Walter J. Steinkraus/
Walter J. Steinkraus
Registration No.: 29592

6640 Shady Oak Dr., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001